DEPARTMENTAL POLICY

POLICY #117	**SUBJECT:** Participation of DSCYF Clients in Research
EFFECTIVE DATE: June 4, 2008	**PAGE** 1 of 2
AUTHORIZED SIGNATURE:	

PARTICIPATION OF DSCYF CLIENTS IN RESEARCH

I. BACKGROUND

The Department recognizes that research and evidence-based practice contribute to the development of safe and effective interventions for children and their families. The Department population is inherently vulnerable, however, and thus warrants special protections.

II. PURPOSE

The purpose of this policy is to assure the safety and the rights of children in the care and custody of the Department when/if there is a request for them to participate as subjects in research protocols. Such requests require the review and approval of the proposed research protocol by an Institutional Review Board (IRB).

III. APPLICABILITY

This policy applies to all workers employed or contracted by the Department and to all Contractors who are providing services to children and families under Departmental funding.

IV. DEFINITIONS

Client – Any minor child (under the age of 18) who is active with the Department.

Institutional Review Board (IRB) – A panel of experts in the content areas of potential research who have the education, training and experience to review research protocols pursuant to the requirements of the United States Department of Health and Human Services Office for Human Research Protections (OHRP). Most universities and hospitals have IRBs as do some large governmental agencies. In addition, there are corporate proprietary entities that are approved through OHRP which provide IRB services.

Human Subjects Research – Research meeting the definition below in which project staff obtain data from people by intervening or interacting with them.

Protocol – The procedures by which an investigator proposes to test a research hypothesis. A protocol often includes terms for recruitment of subjects (e.g. sample size, criteria for excluding or including prospective subjects); data-gathering (e.g. self-report questionnaires, physiological or biological measures); consent for participation (e.g., language in the consent forms that is at an appropriate reading level for the persons who must sign the consent forms, the terms of confidentiality, an explanation of how the data will be used); the conditions to which subjects will be exposed (e.g. treatment); and potential risks vs. benefits of participation.

Research - A systematic investigation , including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

IV. POLICY

Research using Departmental clients as human subjects will not be permitted without documentation of safeguards as specified in the Procedures attached by reference to this policy.

PROCEDURES TO ACCOMPANY DEPARTMENTAL POLICY # 117
PARTICIPATION OF DSCYF CLIENTS IN RESEARCH

The purpose of this document is to assist DSCYF staff at every level in the organization to understand that requests for participation in research may come from different sources; the general principles for protecting the safety and rights of research participants; the different levels of risk that are posed by various types of research; and the Department's procedures for permitting researchers to recruit its clientele and/or client data for research purposes. This document does not attempt to re-state the many federal, state and local protections that currently exist for the DSCYF population.

POTENTIAL SOURCES OF REQUESTS

Requests that Department clients participate in research may come from various sources:

A. Internal requests
    1. Grants – A Divison may seek a grant for a type of service for which outcome data must be submitted and which will be added to other data nationally.
    2. Employees of DSCYF who may be students in college courses or student interns within DSCYF who may wish to gather new or existing data to satisfy course research requirements.

B. Contractor requests
    1. Contractors may seek to publish data on a program serving Departmental clients.
    2. Contractors may wish to collaborate with researchers using the Provider's DSCYF program clients as subjects in a research project or clinical trial.

C. External Requests
    1. A researcher may request that a worker sign informed consent for a child in DFS custody to participate in a research project.
    2. Other persons in DSCYF leadership roles may be requested by a University or other agency to permit clients to be used in a research project.

GENERAL PRINCIPLES

A. Participation of clients in research must be free from coercion or the appearance of coercion.
    1. At no time will youth in DSCYF secure care be permitted to participate in research that requires interaction between research staff and the youth. Use of aggregated data that does not contain identifiable client data about youth in secure care is permitted.
    2. At no time will there be a direct or implied requirement for parents involved with DFS to be required to sign consent for their child to participate in research.

3. At no time will there be a direct or implied requirement for any client to participate in research in exchange for positive consideration from Departmental staff.

B. Participation in research must be with full informed, written consent of the legal authorized representative which has an expiration date of no more than one year and must be renewed at that time. When a child is to be a subject, this is usually a parent or legal guardian. Signed consent may be revoked by the parent or legal guardian at any time.

1. When DFS holds parental rights, the DFS worker may sign informed consent under the conditions listed later in this document.
2. When DFS holds custody, but not parental rights, the DFS worker may sign informed consent under the conditions listed later in this document.

C. Wherever the nature of the project and the developmental level of the child permits, the client should have the opportunity to assent to participation in research in addition to the consent by the legally authorized person.

D. Participation of clients in research in which individual identifiable client information will be gathered and analyzed must be with the assurance that privacy and confidentiality will be maintained pursuant to Federal, State, Departmental and professional standards.

E. Client participation in research should provide a reasonable expectation that participation is likely to yield some direct benefit to the subject and/or that the knowledge generated by the project has the potential to benefit other children/adolescents.

TYPES OF RESEARCH AND RELATIVE RISK TO DSCYF CLIENTS

A. Level 1 - *Little or No Risk to Clients*

This level of research may examine existing aggregate data or may propose to develop data-gathering processes to do outcome studies on an existing program. It does not involve identifiable confidential client information, except for aggregate reporting. There is no interaction between project staff and individual clients for purposes of gathering data upon which to draw conclusions.

B. Level 2 - *Minimal Risk to Clients*

This level of research may look at the effects of an existing or proposed program that uses methodology already accepted within mainstream practice, e.g., trauma-focused cognitive behavioral therapy; functional assessment of infants or toddlers in foster care before and after foster parents receive specialized training for this population; classroom management techniques, etc.

While there is interaction between project staff and individual clients and identifiable information is used in the project, the risk of harm to subjects is no greater, in terms of magnitude or probability, than what is usually experienced in daily life.

C. Level 3 - *Moderate Risk to Clients*

This level of research may use certain types of untried non-invasive diagnostic procedures or treatment techniques. It usually requires assignment of a client to a test condition or to a control-group that will not experience the test condition.

There is interaction between project staff and individual clients that:

- has the potential for some level of physical or emotional discomfort or uneasiness, or
- may assign a client to a group not receiving the expected benefit of the treatment/technique, or
- may introduce a risk of harm that is greater, in terms of magnitude or probability, than what is usually encountered in daily life.

D. Level 4 - *Greater than Moderate Risk to Clients*

This level of research applies to clinical trials for medication, untried diagnostic medical and surgical procedures.

PROCEDURAL SAFEGUARDS FOR PERMITTING DEPARTMENTAL CLIENTS TO BE RESEARCH SUBJECTS

While parents have the exclusive right to approve their child's participation in any research project, and may do so outside the aegis of the Department, participation of DSCYF clients in research under Departmental auspices must have strict safeguards to insure the well-being of children in our care.

A. Level 1 - *Little or No Risk to Clients*

1. Use of non-identifable aggregate Departmental/Divisional data/information by Departmental employees may be approved for research at the level at which the data are produced within the Department. This approval must be documented.
2. Release of non-identifiable aggregate Departmental/Divisional data/information for use by researchers outside the Department must be documented at the division level by the Director for Divisional data, or at the departmental level by the Cabinet Secretary for Departmental data.
3. Researchers may publish their own non-identifiable aggregate data, if this information is not the product of contractual reporting requirements. If the program is fully funded by the Department, the data must first be approved by the contracting Divisions. In

these cases, the name of the program, the Division and the Department must be acknowledged in the publication.

B. For all levels of research beyond Level 1, whether performed internally by Departmental staff or externally by other researchers, Departmental clients may not be considered for participation until the research protocol is reviewed and approved by an *Institutional Review Board* (IRB) that meets all the federal requirements for an IRB. Approval by an IRB must be documented.

DSCYF does not have an IRB. If a potential reseach project needs to have its research protocol reviewed by an IRB, it is recommended that contact be made with the IRB at University of Delaware to see if its IRB could conduct the required review. The Delaware Department of Health and Social Services IRB is able to conduct reviews only for reseach participants who are in services provided by the DHSS.

C. Level 2 - *Minimal Risk to Clients*

1. When DFS holds parental rights for a child, a worker may sign informed consent for the child's participation in research if :
   a. DFS documents receipt of a copy of IRB review and approval which acknowledges 45 CFR § 46.409: Participation of children who are wards of the state, and
   b. The Division Director or his/her designee provides written approval either for a specific child to participate, or in the case of an entire program being provided under Departmental auspices, for an entire class of children to participate.

2. When DFS holds legal custody but does not hold parental rights for a child, a worker may sign informed consent for the child's participation in research if they document:
   a. That DFS has received a copy of IRB review and approval, and
   b. That DFS has documented recent efforts to locate the person who holds parental rights without success, and that failure to sign consent would deprive the child of a service that would benefit him/her or children in similar circumstances, and
   c. The Division Director or his/her designee provides written approval either for a specific child to participate, or in the case of an entire program being provided under Departmental auspices, for an entire class of children to participate.

3. If a DSCYF Program Administrator/Contract Manager receives a request from a Contractor to perform research in a DSCYF program, using DSCYF clients at any level, he/she may provide permission if the following are documented:
   a. The Contractor provides a copy of the IRB review and approval for the research protocol, and
   b. The proposed research is intended to support the development of evidence-based practices in the program and can be reasonably expected to improve the quality of services to be provided, and
   c. The Division Director or his/her designee is consulted and approves in writing.

D. Level 3 - *Moderate Risk to Clients*

Participation of Departmental clients in research at this level of risk is discouraged, although there may be rare instances when the benefits to a child or children may warrant the additional risk.

1. All requests for DSCYF client participation in research at this level must go through the Division Director, who will examine the IRB review and approval, weigh the risks and benefits to clients, seek appropriate professional advice, including consultation with the Cabinet Secretary, if required, before making a decision.
2. The Division Director will designate in writing, what, if any, DSCYF/DFS worker may sign informed consent for a client's participation where parents are not available.

E. Level 4 - *Greater than Moderate Risk to Clients*

On very rare occasions, an individual child for whom DFS holds parental rights may have a serious medical condition in which failure to provide an experimental treatment would result in serious physical impairment or death. These are the only situations in which a DSCYF client may participate in research at this level of risk. On these occasions, only the Cabinet Secretary, or his/her designee may provide permission. This permission must be documented.